

(19) World Intellectual Property Organization
International Bureau



10/529655

(43) International Publication Date
15 April 2004 (15.04.2004)

PCT

(10) International Publication Number
WO 2004/031354 A3

(51) International Patent Classification⁷: C07H 21/02

(21) International Application Number:
PCT/US2003/030870

(22) International Filing Date:
30 September 2003 (30.09.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
10/260,708 30 September 2002 (30.09.2002) US

(71) Applicant (for all designated States except US): LUDWIG INSTITUTE FOR CANCER RESEARCH [CH/US]; 605 Third Avenue, New York, NY 10158 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): SCANLAN, Matthew, J. [US/US]; Ludwig Institute for Cancer Research, 605 Third Avenue, New York, NY 10158 (US). LEE, Sang-Yull [US/US]; Ludwig Institute for Cancer Research, 605 Third Avenue, New York, NY 10158 (US). OLD, Lloyd, J. [US/US]; Ludwig Institute for Cancer Research, 605 Third Avenue, New York, NY 10158 (US).

(74) Agent: VAN AMSTERDAM, John, R.; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210 (US).

(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:
12 January 2006

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



WO 2004/031354 A3

(54) Title: HUMAN SARCOMA-ASSOCIATED ANTIGENS

(57) Abstract: The invention relates to sarcoma-associated antigens and the nucleic acid molecules that encode them. The invention further relates to the use of the nucleic acid molecules, polypeptides and fragments thereof associated with sarcoma in methods and compositions for the diagnosis and treatment of diseases, such as cancer. More specifically, the invention relates to the discovery of a novel cancer/testis (CT) antigen, NY-SAR-35.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/30870

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C07H 21/02

US CL : 536/23.1

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 536/23.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MEDLINE, STN, WEST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/40466 A2 (GENENTECH, INC.) 07 June 2001, Sequence 15 and page 5 lines 12-17	1, 5, 10, and 11

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

19 October 2005 (19.10.2005)

Date of mailing of the international search report

23 NOV 2005

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner of Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Authorized officer

Sean E. Adler, Ph.D.

Facsimile No. (703) 305-3230

Telephone No. 571-272-1600

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/30870

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1-13 and 158-159, searched to the extent that the claims encompass SEQ ID NO:1

Remark on Protest

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The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

PCT/US03/30870

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Groups 1-25, claim(s) 1-13 and 158-159, drawn to the special technical feature of an isolated nucleic acid molecule selected from the group consisting of SEQ ID NOs: 1-14 and 97-107.

Upon payment and selection of any one of groups 1-25 above, Applicant must identify ONE corresponding SEQ ID NO. If no extra search fees are paid, group 1 will be searched to the extent that it encompasses SEQ ID NO:1.

Groups 26-50, claim(s) 14 and 15, drawn to the special technical feature of an isolated polypeptide selected from a polypeptide encoded by a sequence selected from the group consisting of SEQ ID NOs: 1-14 and 97-107.

Upon payment and selection of any one of groups 26-50 above, Applicant must identify ONE corresponding SEQ ID NO.

Groups 51-75, claim(s) 16 and 17, drawn to the special technical feature of an isolated binding polypeptide that selectively binds to an isolated polypeptide encoded by a sequence selected from the group consisting of SEQ ID NOs: 1-14 and 97-107.

Upon payment and selection of any one of groups 51-75 above, Applicant must identify ONE corresponding SEQ ID NO.

Groups 76-120, claim(s) 18-27 and 160-161, drawn to the special technical feature of a method of diagnosing cancer in a subject comprising determining the presence of an antibody that binds a polypeptide encoded by a sequence selected from the group consisting of SEQ ID NO: 3, 5-8, 10-45, 99, 102, 104, and 108.

Upon payment and selection of any one of groups 76-120 above, Applicant must identify ONE corresponding SEQ ID NO.

Groups 121-165, claim(s) 28-47 and 162-163, drawn to the special technical feature of a method of diagnosing cancer in a subject comprising determining the expression of an antigen wherein the antigen or nucleic acid molecule that encodes it is encoded by a sequence selected from the group consisting of SEQ ID NO: 3, 5-8, 10-45, 99, 102, 104, and 108.

Upon payment and selection of any one of groups 121-165 above, Applicant must identify ONE corresponding SEQ ID NO.

Groups 166-210, claim(s) 48-64 and 164-165, drawn to the special technical feature of a method for determining the onset, progression, or regression of cancer in a subject wherein the nucleic acid molecule is encoded by a sequence selected from the group consisting of SEQ ID NO: 3, 5-8, 10-45, 99, 102, 104, and 108.

Upon payment and selection of any one of groups 166-210 above, Applicant must identify ONE corresponding SEQ ID NO.

Groups 211-255, claim(s) 65-69 and 166, drawn to the special technical feature of a kit comprising one or more sarcoma-associated antigens encoded by a sequence selected from the group consisting of SEQ ID NO: 3, 5-8, 10-45, 99, 102, 104, and 108.

Upon payment and selection of any one of groups 211-255 above, Applicant must identify ONE corresponding SEQ ID NO.

Groups 256-300, claim(s) 70-76, drawn to the special technical feature of a kit comprising one or more binding agents that specifically bind to a sarcoma-associated antigen wherein the nucleic acid molecule is encoded by a sequence selected from the group consisting of SEQ ID NO: 3, 5-8, 10-45, 99, 102, 104, and 108.

Upon payment and selection of any one of groups 256-300 above, Applicant must identify ONE corresponding SEQ ID NO.

Groups 301-345, claim(s) 77-91, 167, and 177, drawn to the special technical feature of a method of treating a subject comprising administering an antibody or antigen-binding fragment that specifically binds to a polypeptide encoded by a sequence selected from the group consisting of SEQ ID NO: 3, 5-8, 10-45, 99, 102, 104, and 108.

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Upon payment and selection of any one of groups 301-345 above, Applicant must identify ONE corresponding SEQ ID NO.

Groups 346-390, claim(s) 92-106, 168-169, and 178, drawn to the special technical feature of a method of treating a subject comprising administering an amount of an agent that selectivity binds to the sarcoma-associated antigen or the nucleic acid molecule that encodes it wherein the sequence is selected from the group consisting of SEQ ID NO: 3, 5-8, 10-45, 99, 102, 104, and 108.

Upon payment and selection of any one of groups 346-390 above, Applicant must identify ONE corresponding SEQ ID NO.

Groups 391-435, claim(s) 107-120, 170-171, and 179, drawn to the special technical feature of treating a subject comprising administering an agent which stimulates an immune response to a sarcoma-associated antigen encoded by a sequence selected from the group consisting of SEQ ID NO: 3, 5-8, 10-45, 99, 102, 104, and 108.

Upon payment and selection of any one of groups 391-435 above, Applicant must identify ONE corresponding SEQ ID NO.

Groups 436-480, claim(s) 121-125 and 172, drawn to the special technical feature of a kit for diagnosing a disorder associated with the aberrant expression of a sarcoma-associated antigen or a nucleic acid molecule that encodes it wherein the sequence is selected from the group consisting of SEQ ID NO: 3, 5-8, 10-45, 99, 102, 104, and 108.

Upon payment and selection of any one of groups 436-480 above, Applicant must identify ONE corresponding SEQ ID NO.

Group 481, claim(s) 126-130, drawn to the special technical feature of a method for identifying a cancer-associated antigen.

Group 482-526, claim(s) 131-143, 173-174, and 180, drawn to the special technical feature of a composition comprising an agent which stimulates an immune response to a sarcoma-associated antigen encoded by a nucleic acid molecule selected from the group consisting of SEQ ID NO: 3, 5-8, 10-45, 99, 102, 104, and 108.

Upon payment and selection of any one of groups 482-526 above, Applicant must identify ONE corresponding SEQ ID NO.

Group 527-538, claim(s) 144-157 and 175-176, drawn to the special technical feature of an agent which selectively binds to a sarcoma-associated antigen or a nucleic acid molecule that encodes it wherein the nucleic acid molecule is selected from the group consisting of SEQ ID NOs: 3, 5-8, 10-13, 99, 102, and 104.

Upon payment and selection of any one of groups 527-538 above, Applicant must identify ONE corresponding SEQ ID NO.

The technical feature linking groups 1-538 appears to be that they all relate to an isolated nucleic acid molecule selected from the group consisting of (a) complements of nucleic acid molecules which hybridize under high stringency conditions to a nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of nucleotide sequences set forth as SEQ ID Nos: 1-14 and 97-107 and which code for a sarcoma-associated antigen, (b) nucleic acid molecules that differ from the nucleic acid molecules of (a) in codon sequence due to degeneracy of the genetic code, and (c) complements of (a) or (b).

However, Baker et al. (WO0140466; June 2001) teaches a sequence (sequence 15) that would hybridize under high stringency conditions to SEQ ID NO:1 of the instant Application.

Therefore, the technical feature linking the inventions of groups 1-538 does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the art.

Accordingly, groups 1-538 are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.